

6667. King's Phylogene powder. (F.D.C. No. 45840. S. No. 31-822 R.)

QUANTITY: 187 btls. at Montgomery, Ala.

SHIPPED: 12-20-60, from Greenville, S.C., by Libby, Edwards & Brown, Inc.

LABEL IN PART: "King's Phylogene Powder 6 Ounces Ingredients: Potassium Alum - Lactose - Zinc Sulfocarbolate and Thymol. Directions: * * * As a Douche * * * Distributed By: King Pharmaceutical Co., Inc., P.O. Box 1925, Montgomery, Ala. 6012089."

LIBELED: 6-15-61, M. Dist. Ala.

CHARGE: 502(f)(2)—when shipped, the labeling of the article failed to bear a warning against use more than twice weekly unless directed by a physician.

DISPOSITION: 6-23-61. Consent—claimed by King Pharmaceutical Co., Inc., and relabeled.

6668. Electronic Magnetic device. (F.D.C. No. 45921. S. No. 57-799 R.)

QUANTITY: 1 device at St. Petersburg, Fla.

SHIPPED: 4-29-60, from Tiffin, Ohio, by L. L. Roby Mfg. Co.

LABEL IN PART: "Electronic Magnetic Model G."

RESULTS OF INVESTIGATION: Examination indicated that the article was a suitcase-type unit which, on opening, displayed a control panel and detector plates. The control panel contained an array of switches, dials, push buttons, electrode terminals, and indicator lights. Electronic components within the case formed a power supply, oscillator, and amplifier for the detection and/or operation of hertzian waves.

LIBELED: 6-2-61, S. Dist. Fla.

CHARGE: 502(b)(1)—when shipped and while held for sale, the device failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor; and 502(f)(1)—the labeling of the article failed to bear adequate directions for use and it was not feasible to devise any directions for use because the article was worthless for any medical purposes.

DISPOSITION: 7-10-61. Default—delivered to the Food and Drug Administration.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS**6669. Menodol tablets. (F.D.C. No. 45594. S. No. 35-880 R.)**

QUANTITY: 9 cases, each containing 24 50-tablet btls., at Santurce, P.R.

SHIPPED: 10-3-60, from New York, N.Y., by Darro Pharmacal Co., Inc.

LABEL IN PART: (Btl.) "Menodol Improved Each Menodol Tablet Contains: Mephenesin * * * 250 mg. Sodium Salicylate 200 mg. Sodium Gentisate 100 mg. * * * Darro Pharmacal Co., Inc., New York, N.Y. Distributors."

RESULTS OF INVESTIGATION: Analyses showed that the article contained mephenesin, 37 percent; sodium salicylate, 37 percent; and sodium gentisate, 49 percent, of the labeled amount.

LIBELED: 3-24-61, Dist. P.R.

CHARGE: 501(c)—when shipped, the strength and quality of the article fell below that which it purported to possess; and 502(a)—the label statements "Each Menodol Tablet Contains: Mephenesin * * * 250 mg. Sodium Salicylate 200 mg. Sodium Gentisate 100 mg." were false and misleading as